REPLY UNDER 37 C.F.R. §1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 1652

PATENT
Attorney Docket No. 27866/32960

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Patrick Gray
Serial No:	08/663,618
Filed:	June 14, 1996
Title:	Chitinase Materials and Methods
Group Art Unit:	1652
Examiner:	R. Prouty

CERTIFICATE OF MAILING
(37 CFR 1.8)

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service as first class mail, postage prepaid, on November 18, 2002 in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Thomas J. Wrona, Ph.D.

AMENDMENT AND RESPONSE
AFTER FINAL REJECTION UNDER 37 C.F.R. 1.116

Commissioner for Patents
Box AF
Washington, D.C. 20231

Sir:

This is in response to the final Office Action dated July 16, 2002. A Petition for a One Month Extension of Time is filed herewith extending the time for response to November 16, 2002. Applicants note with appreciation that the Examiner has indicated that claims 1-12 have been allowed.

I. Outstanding Rejections

Claims 13-18 and 32 remain rejected under 35 U.S.C. § 112, second paragraph.

Claim 32 stands rejected under 35 U.S.C. § 112, first paragraph.

III. Patentability Arguments

A. The Rejection Under 35 U.S.C. § 112, Second Paragraph

The Office Action of July 16, 2002 holds claims 13 (and dependent claims 14-18) and 32 allegedly indefinite for reciting "stringent conditions." The Examiner contends that the meaning of the term may differ based on the individual situation or person making the determination. However, Applicant respectfully submits that this does not render the term indefinite under 35 U.S.C. § 112, second paragraph.

Whether a claim is invalid under 35 U.S.C. § 112, second paragraph, requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. Orthokinetics, Inc. v. Safety Travel Chairs, Inc. 1 U.S.P.Q.2d 1081 (Fed. Cir. 1986). The last paragraph of page 4 of the specification provides exemplary stringent hybridization conditions. It also explains that those of skill in the art understand that variation based on the individual situation occurs, but that formulas standard in the art are appropriate for determining the exact conditions (citing Sambrook *et al.,* 9.47-9.51 in *Molecular Cloning*, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York (1989). Thus, using the specification as a guide along with his knowledge and experience, one of ordinary skill in the art would understand the meaning of "stringent conditions" under any individual condition.

Furthermore, regarding the alleged subjectivity of the term, the fact that different individuals in the art may have different subjective meanings for "stringent conditions" does not render the term indefinite. Applicant notes that compliance with 35 U.S.C. § 112, second paragraph, is generally a question of law. Orthokinetics. In determining the definiteness of a term, an objective determination must be made of the term's meaning to the fictitious "one of ordinary skill in the art." Applicant submits that, in light of the specification and the knowledge of one of ordinary skill in the art, the meaning of "stringent conditions" can be

determined. Applicant respectfully requests reconsideration of the indefiniteness of claims 13 (and dependent claims 14-18) and 32 for containing the term "stringent conditions."

The Office Action also finds claim 32 allegedly indefinite for reciting "immunogenic fragment." In light of the specification (see page 6, lines 3-4, and 23-25), one of ordinary skill in the art would understand the term to mean a fragment that will induce an antibody to the human chitinase of SEQ ID NO:2. Conditions for testing antibody-antigen binding are standard in the art and the necessary specificity would be well understood by one of ordinary skill in the art. Applicant respectfully requests withdrawal of the rejection of the claims under 35 U.S.C. § 112, second paragraph.

B. The Rejection Under 35 U.S.C. § 112, First Paragraph

Given that the term "immunogenic fragment" would be understood by one of ordinary skill in the art to mean a fragment that will induce an antibody to the human chitinase of SEQ ID NO:2, the claimed genus of nucleic acids is well defined both structurally and functionally. Structurally, the claimed purified, isolated polynucleotides are limited to those of double-stranded DNA comprising the protein coding portion of the sequence set out in SEQ ID NO:1 and DNAs that contain sufficient homology to SEQ ID NO:1 such that they hybridize thereto under stringent conditions. Functionally, all the claimed polynucleotides encode human chitinase of SEQ ID NO:2 or an immunogenic fragment thereof. Thus, the specification provides exemplary polynucleotides that satisfy the structural and functional limitations of claim 32. Applicant is not required to disclose every embodiment included within the scope of the claims. Using the specification as a guide, one of ordinary skill in the art, without undue experimentation, could make and use every embodiment having the structural and functional limitations of claim 32.

Furthermore, irrespective of how diverse the embodiments within the scope of the claims are, Applicant was in possession of the claimed "genus" at the time the application

was filed. In the first paragraph of the Summary of the Invention (page 3), the specification reads "the present invention provides novel purified and isolated polynucleotides...encoding human chitinase or fragments and analogs thereof." In the next paragraph, the specification describes "purified, isolated polynucleotides encoding human chitinase amino acid sequence of SEQ ID NOS: 2 or 4" (lines 17 and 18) and "(a) a double-stranded DNA comprising the protein coding portions of the sequence set out in SEQ ID NO: 1, (b) a DNA which hybridizes under stringent conditions to a non-coding strand of the DNA of (a)" (lines 24-26). DNA encoding immunogenic fragments is described at least on page 5, line 31, to page 6, live 4. Thus, as evidenced by the specification, Applicant was in possession of the claimed "genus" of polynucleotides at the time of filing. Applicant respectfully requests withdrawal of the rejection of claim 32 under 35 U.S.C. § 112, first paragraph.

IV. Conclusion

In light of the foregoing amendments and remarks, it is submitted that all claims should be allowed. Should the Examiner wish to discuss any further material of form or substance, she is encouraged to contact the undersigned agent at the telephone number listed below.

Respectfully submitted,

MARSHALL, GERSTEIN & BORUN

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November 18, 2002

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AMENDMENT TRANSMITTAL LETTER

Docket No. 27866/32960

Application No.	Filing Date	Examiner	Art Unit
08/663,618	June 14, 1996	Rebecca Prouty	1652

Applicant(s): Patrick W. Gray

Invention: CHITINASE MATERIALS AND METHODS

TO THE COMMISSIONER FOR PATENTS

Transmitted herewith is an amendment in the above-identified application.

The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED					
	Claims Remaining After Amendment	Highest Number Previously Paid	Number Extra Claims Present	Rate	
Total Claims	19	- 32 =		x	0.00
Independent Claims	5	- 5 =		x	0.00
Multiple Dependent Claims (check if applicable)	☐				
Other fee (please specify):	Extension for response within first month				110.00
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT:					110.00

☒ Large Entity ☐ Small Entity

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☒ A check in the amount of $ 110.00 to cover the filing fee is enclosed.

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Dated: November 18, 2002

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Dated: November 18, 2002 Signature: _____ (Thomas J. Wrona, Ph.D.)